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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,014	10/28/2003	Constantin Polychronakos	MGU-0020	4261

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EXAMINER	
MALLARI, PATRICIA C	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 05/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,014	POLYCHRONAKOS ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 7-10* is/are rejected.

7)☒ Claim(s) *4-6 and 11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,919,770 to Preidel et al. (Preidel '770) in view of US Patent No. 6,645,368 to Beaty et al. Preidel '770 discloses a glucose quantification device for determining the concentration of glucose in a liquid medium (col. 2, lines 13-33 of Preidel '770). The device comprises a reference electrode (BE), a counter electrode (GE), and a working electrode (AE) with a semipermeable membrane (fig. 2; col. 3, lines 34-40; col. 4, lines 6-24 of Preidel '770). Preidel '770 fails to explicitly state that the sensor is immersed in the liquid medium. However, the presence of a protein- or other large molecule-blocking membrane would not be necessary if the sensor were not immersed in the fluid medium. Therefore, the sensor must inherently be used such that at least the membrane is immersed in such liquid medium. A potentiostat 11 applies a measurement potential to the working electrode AE relative to the reference electrode BE during at least a portion of a measurement period, thereby causing said chemical entity to participate in n electrochemical reaction resulting in an effect on impedance (col. 5, lines 39-50 of Preidel '770). A measuring unit 12, 13 obtains an impedance measurement (col. 5, lines 50-59 of Preidel '770). Preidel '770 states that a computer 13 determines the concentration from the impedance but is silent as to how.

However, Beaty discloses a means 54 for determining glucose concentration from impedance measurements taken from a biosensor in contact with a bodily fluid, wherein the impedance measurement is compared with a calibration standard to obtain a comparison result, or glucose concentration (col. 10, lines 11-48 of Beaty). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the means of determining glucose concentration of Beaty as the means for determining glucose concentration of Preidel '770, since Preidel '770 discloses a means for determining glucose concentration from impedance measurements and Beaty describes an appropriate such means.

Regarding claims 2 and 3, the liquid medium is blood and the chemical entity is glucose (col. 1, lines 17-29; col. 2, lines 13-15 of Preidel '770).

Regarding claim 8, the counter electrode is platinum (col. 4, lines 15-19 of Preidel '770).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Preidel '770 in view of Beaty, as applied to claims 1-3 and 8 above, and further in view of US Patent No. 5,126,034 to Carter et al. Preidel '770, as modified, teaches a reference electrode made of mercury and mercury chloride, rather than Ag/AgCl (col. 4, lines 20-23 of Preidel '770). However, Carter teaches that a reference electrode may Ag/AgCl or mercury and mercury chloride (col. 2, lines 40-42 of Carter). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use an Ag/AgCl electrode as the reference electrode instead of the mercury and mercury chloride

electrode in the device of Preidel '770, as modified by Beaty, since Carter teaches the two materials to be functionally equivalent materials for a reference electrode.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,665,065 to Colman et al. in view of Preidel '770 and Beaty. Colman discloses a method of measuring a glucose concentration level in a patient's blood using an implantable (immersed) glucose sensor 16, determining whether the insulin in the patient's blood is within a normal range, and administering an amount of insulin via a feedback loop pump 10 to the patient to modulate the concentration of the insulin in the liquid medium and regulate glucose levels (col. 3, lines 51-58; col. 4, lines 11-24 of Colman). Colman lacks measuring the impedance of and comparing the impedance measurement with a calibration standard to determine the glucose concentration level.

However, Preidel '770 discloses an implantable sensor comprising a reference electrode (BE), a counter electrode (GE) and a working electrode (AE) with a semipermeable membrane, for determining the concentration of glucose in blood (col. 1, lines 17-19; col. 2, lines 13-15; col. 3, lines 34-37; col. 4, lines 10-38 of Preidel '770). In order to determine the glucose concentration, a measurement potential is applied to the working electrode (AE) relative to the reference electrode (BE), resulting in an effect on impedance (col. 5, lines 39-50 of Preidel '770). The impedance is measured and the glucose concentration is determined therefore (col. 5, lines 50-60 of Preidel '770). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the glucose sensor of Preidel '770 as the glucose sensor in the system of Colman in order to reliably determine glucose concentrations even in the presence of

urea and/or amino acids (col. 1, lines 45-49; col. 3, lines 56-58; col. 6, lines 3-6 and lines 19-21 of Preidel '770). Colman, as modified by Preidel '770, is silent as to how the glucose concentration is derived from the impedance measurement.

However, Beaty discloses a glucose concentration sensor, wherein the glucose concentration is determined form the measured impedance by comparing the impedance measurement with a calibration standard (col. 10, lines 11-48 of Beaty). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the method of determining the glucose concentration from the impedance measurement of Beaty in the method of Colman, as modified by Preidel '770, since Colman, as modified, discloses determining glucose concentration from an impedance measurement, and Beaty describes an appropriate method and means of doing so.

Allowable Subject Matter

Claims 4-6 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 4 and 5, the prior art of record fails to teach or fairly suggest a glucose quantification device comprising the combination of a working electrode comprising a semiconductor wherein the semiconductor surface is covered with immobilized Concanavalin A which binds glucose with a reference electrode, working

electrode, membrane, and potentiostat, wherein the potentiostat applies a measurement potential to the working electrode relative to the reference electrode and a measuring unit obtains an impedance measurement, which is compared with a calibration standard to obtain a comparison result, in combination with all of the other limitations of the claims.

Regarding claim 6, the prior art of record fails to teach or fairly suggest a glucose quantification device comprising a working electrode, wherein the working electrode comprises the combination of a silicon chip containing at least one surface covered with a thin layer of silicon oxide, and a measuring unit measures an impedance measurement resulting from the application of a potential to the working electrode relative to the reference electrode, in combination with all of the other limitations of the claim.

Regarding claim 11, the prior art of record fails to teach or fairly suggest a method of modulating glucose in a patient comprising the step of determining a specific DNA sequence melting temperature (T_m) by continuously determining the impedance value over a period of time while increasing the temperature of the liquid medium, in combination with all of the other limitations of the claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 5,704,354 to Preidel et al.

US Patent No. 6,083,366 to Higson.

US Patent No. 5,225,063 to Gumbrecht et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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